



Title:	Standard Operating Procedures for Product Tracing
Issue Date:	5/2/2015
Effective Date:	5/9/2015

PURPOSE:

To ensure Safe Chain Solutions is compliant with all aspects of the FD&C Act.

INSTRUCTIONS:

All SCS personnel will read and understand this Standard Operating Procedure so the proper steps are taken, when possible to ensure that the company operates in compliance with DCSCA.

PROCEDURES:

1. Product Tracing Information Exchange

a. Safe Chain Solutions will maintain all product tracing information for a minimum of 6 years. The Track and Trace portal created and maintained by SCS personnel will be updated at the close of business each day to show SCS customer transactions. Each customer will have their own log in to download their transaction histories from Safe Chain. Each transaction history will remain on file for a minimum of 6 years.

b. SCS personnel responsible for the sale and purchase of products will all be thoroughly trained on the criterion that defines a product and a transaction. Employees should reference section 581 (13) of the Federal Food, Drug, and Cosmetic Act for clear definitions of products and section 581 (24) for transactions.

c. The transaction information must have all of the following information to be considered complete: Established name of the product, Strength and dosage form, national drug code, container size, number of containers, lot number of the product, transaction date, date of shipment, and business name and address of the seller and buyer.

2. Product Transaction History

a. Safe Chain Solutions must have the transaction history supplied by the trading partner SCS is purchasing the product from. The history may be paper or electronic. The information must include every transaction relating to the product including the manufacturer's information.

3. Product Transaction Statement

a. The product transaction history must contain the following information from the entity that is transferring ownership.

- Is authorized as required under the DSCSA
- Received the product from a person that is authorized under the DSCSA
- Received transaction history and transaction statement from the prior owner as required by law
- Did not knowingly ship a suspect or illegitimate product
- Had systems and processes in place to comply with





validation requirements by law

- Did not knowingly provide false transaction information
- Did not knowingly alter the transaction history



4. Direct Purchase Statements

a. When purchasing a product directly from a manufacturer, exclusive distributor of a manufacturer or a repackager, Safe Chain must always have a direct purchase statement before accepting ownership of the product.

5. Accepting ownership

a. Under no circumstances should Safe Chain Solutions accept ownership of any product without the transaction history, transaction information and transaction statement.